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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------------|
| 10/630,143 | 07/30/2003 | Kenneth W. Hunter | IMMUSONIC-005-1 | 9478 |
| 21897 7590 06/06/2007 THE MATTHEWS FIRM 2000 BERING DRIVE SUITE 700 HOUSTON, TX 77057 | | | EXAMINER OUSPENSKI, ILIA I | |
| | | | ART UNIT 1644 | PAPER NUMBER |
| | | | MAIL DATE 06/06/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/630,143 | Applicant(s) HUNTER ET AL. | |
| | Examiner ILIA OUSPENSKI | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to ILIA OUSPENSKI, Group Art Unit 1644, Technology Center 1600.

2. Applicant's amendment/remarks, filed on 08/22/2006, are acknowledged.

Claims 2 – 10 and 13 – 23 have been cancelled.

Claims 1 and 11 – 12 are pending.

3. This Office Action will be in response to Applicant's amendment and arguments, filed on 08/22/2006.

The rejections of record can be found in the previous Office Action, mailed on 02/22/2006.

4. Claim 1 is objected to because of the following informalities: in the recitation of "B" glucans it appears that "beta" was intended. Appropriate correction or clarification is required.

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5. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 11 – 12 stand rejected under **35 U.S.C. 102(b)** as being anticipated by Rorstad et al. (US Patent No. 5,401,727; of record; see entire document), for the reasons of record.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant asserts that that the claimed invention is neither disclosed, taught, or suggested by the cited references, but provides no support or reasoning for this assertion, other than to state that Rorstad et al. describe the use of glucopyranose units linked by beta glycosic bonds.

In contrast to Applicants assertion, the teachings of Rorstad et al. anticipate the instant claimed invention, for the reasons set forth below.

The instant claim 1 is directed to a method, which recites a single method step, specifically administering a composition containing a beta-1,3-glucan or beta-1,6-glucan to an animal or a human.

Rorstad et al. teach a method comprising a step of administering beta-1,3-glucan and beta-1,6-glucan to an animal (see entire document, in particular, e.g. the

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Abstract). As such, Rorstad et al. teach administering the same substance to the same subject as instantly claimed, and therefore, there is no manipulative difference between the prior art method instant claimed invention, even though the reference is silent about the effect on B7 molecules or differentiation of T lymphocytes. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). “[i]t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable”. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

The instant claim 11 is directed to a method, comprising the steps of preparing beta-1,3-glucan, conjugating it to a vaccine, and administering it to an animal or a human.

Rorstad et al. present extensive teachings of the methods of preparation of glucans for administration to animals (see entire document, e.g. columns 5 – 7). The reference also teaches that glucans can be administered along with vaccine antigens (e.g. the Abstract), i.e. as adjuvants. In view of these teachings, a skilled artisan would at once envisage conjugating the vaccine antigens to the glucan (adjuvant), such conjugation being routine in the art.

With regard to the limitations of claim 12, it is noted that since Rorstad et al. teach the same glucans as instantly recited, their composition is inherently the same.

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Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

7. Conclusion: no claim is allowed.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.

Patent Examiner

Art Unit 1644

May 30, 2007

Phillip Gambel

PHILLIP GAMBEL, PH.D. *JS*
PRIMARY EXAMINER

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5/30/07